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PCT/NZ03/00243

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 26 September 2003 with an application for Letters Patent number 528536 made by FISHER & PAYKEL HEALTHCARE LIMITED.

PRIORITY DOCUMENT
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Dated 6 November 2003.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

COMMISSIONER OF PATENTS, TRADEMARKS & DESIGNS
NEW ZEALAND

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528536

NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"Breathing Assistance Apparatus"

We, FISHER & PAYKEL HEALTHCARE LIMITED, a company duly incorporated under the laws of New Zealand of 15 Maurice Paykel Place, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

FIELD OF INVENTION

The present invention relates to humidification particularly though not solely to humidifying gases to a user requiring Continuous Positive Airway Pressure (CPAP).

SUMMARY OF THE PRIOR ART

It is known in the art to provide CPAP treatment in conjunction with humidity, see for example United States Patent Number 6,050,260. The humidification is usually provided either by:

1. An integrated CPAP blower and humidifier as described in US 6,050,260, whereby there is no separation of the CPAP and heated humidifier except for the humidification chamber for filling and cleaning.
2. A standalone CPAP device connected by a flexible airway tube to a standalone heated humidifier, the equipment generally mounted on a tray for stability.
3. A CPAP device that can standalone but can also be combined to a heated humidifier in a way that it appears, when combined, to be a single piece of equipment. No flexible airway tube nor a mounting tray is required.

It would be desirable to provide a CPAP device which could be easily upgraded to provide humidification.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a breathing assistance apparatus which goes someway to achieving the abovementioned desiderata, overcoming the abovementioned disadvantages or at least provides the public with a useful choice.

Accordingly in a first aspect the present invention may be broadly said to consist in a breathing assistance apparatus comprising

a gas delivery device adapted to provide gas at a substantially positive mean pressure;

a humidifier adapted to humidify said gas and;

means for providing at least two configurations, a first configuration with a predetermined functionality inoperable with said gas delivery device operable and a

second configuration with said predetermined functionality and said device operable.

In a second aspect the present invention may be broadly said to consist in a breathing assistance apparatus comprising:

means for providing gas at a substantially positive mean pressure;

means for humidifying said gas; and

means for providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

In a third aspect the present invention may be broadly said to consist in a method of delivering respiratory gases to a patient comprising the steps of:

providing gas at a substantially positive mean pressure;

humidifying said gas; and

providing at least two configurations, a first configuration with a predetermined functionality inoperable and a second configuration with said predetermined functionality.

Wherein said predetermined functionality is active humidification wherein said means adapted such that said second configuration is initiated by the engagement of a predetermined mechanical key with said apparatus.

Alternatively said means adapted such that said second configuration is initiated by the engagement of a predetermined magnetic key with said apparatus.

In a further alternative said means adapted such that said second configuration is initiated by the entry of a predetermined code into a keypad on said apparatus.

In a still further alternative a portion of said apparatus may be separated corresponding to said first configuration, whereby the integration of said portion corresponds to said second configuration.

In a still further alternative said second configuration is initiated by a software or hardware dongle supplied to said apparatus.

Wherein said apparatus further comprises a conduit between the device and the patient and heater within or incorporated with said conduit.

Wherein said predetermined functionality relates to said heater heating said gas.

Alternatively said predetermined functionality relates to storage or display of data

relating to the use of said apparatus.

Alternatively said predetermined functionality relates to the pressure level, or the variation thereof, delivered to the patient.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

BRIEF DESCRIPTION OF THE DRAWINGS

One preferred form of the present invention will now be described with reference to the accompanying drawings in which

Figure 1 is a perspective view of the CPAP only configuration;

Figure 2A is a blown out view of the CPAP only configuration;

Figure 2B is a reverse angle of figure 2A;

Figure 3 is a perspective view of the humidified CPAP configuration;

Figure 4 is a front view showing another example control panel; and

Figure 5 is a front view showing an alternative control panel.

DETAILED DESCRIPTION

A typical integrated CPAP humidifier is described in United States Patent No. 6,050,260. The contents of which are incorporated herein by reference.

The present invention may include an integral, separable or separate humidifier which may be selectively configured to an inoperative or operative state. The switch over is dependent on the user or the seller having access to an actuation tool (described later) to activate the humidifier.

Referring to Figure 1 the CPAP device 100 is initially available for use as a

standalone CPAP. The heater plate being isolated by a covering shroud 102, the shroud also forms a connection port for the CPAP blower outlet 104. The heated humidification hardware being disabled by the absence of the activation tool.

Upgrade to a CPAP device including heated humidification is completed by the installation of the actuation tool. Removal of the heater plate isolating shroud 102 shown in Figure 3, and/or installing the actuation tool enables the software controlled heated humidification hardware 106 for heated humidifier operation.

Examples of the various forms of actuation tool could include:

1. Software key via serial data port

The CPAP device could be connected via RS232 serial connection to a computer or directly via TCP/IP or telephone line to the Internet to receive either additional software or coded actuation data.

2. Mechanical Key

The heater plate vestibule is covered by a shroud. A mechanical key (110, Figure 2A) is used to remove the shroud. The heater plate control knob 108 is locked off by the shroud 102 as shown in Figure 2A. The upgrade kit may include a knob to turn the heater plate on. In one embodiment shown in Figures 2A & 2B engaging the key 110 pushes two snap fit flanges 112, allowing the shroud 102 to be removed.

3. Magnetic Key

Also includes a shroud as in Figure 2 but in addition there is a key which has magnets in a predetermined pattern. This key is slid into a cavity in the case. Inside the case there are Hall effect sensors that defect the pattern of magnets. If the key is detected, the heater plate is activated.

4. Code Number Verification

Also includes a shroud as in Figure 2 but in addition there is a code number that is entered into the device. The dealer phones a freephone number with the serial number of the CPAP device and pays for the upgrade. The freephone service then gives the dealer a code number that is specific to the serial number of the CPAP device. This code number is then entered into a keypad (not shown) to activate the humidifier.

The freephone service could also be an Internet based service.

Another alternative is that the upgrade kit includes a card with a number hidden inside the packaging. This number then gives the freephone service evidence that the dealer has paid for the kit, and the financial transaction then doesn't have to be conducted on the phone. Similarly to prevent fraud the numbers could be stored such that if a number is used twice an alarm is raised.

5. Dongle

A plug in pack containing an electronic circuit designed to respond in a predetermined way to interrogation by the CPAP device. The plug in pack could plug into a dedicated socket in the device or into the existing serial port. Similarly a smart card of known type could be interfaced with the CPAP device to activate the humidifier.

Additionally, the dongle may contain some of the electronic circuit needed to operate the heater plate. Again a shroud as seen in Figures 1 and 2 would be required.

6. Removable Heater Plate

The CPAP device is supplied with a plastic cradle where the heater plate currently is. The plastic cradle has all of the mounting and springing arrangement that the current heater plate has. the cradle also has an electrical connector and clips. A second part consisting of the pressed metal heater plate top surface with the element, thermistor and thermal cutout bonded to it is then supplied in the upgrade kit. The dealer can then remove the shroud and plug the heater plate into the cradle. The plastic cradle means that the fixings and spring mechanism can be preassembled inside the unit so that the heater plate can be installed without tools and without the need to disassemble the unit.

It will be appreciated that while in the preferred embodiment the unhumidified CPAP configuration utilises a shroud over the heater plate, this is not required. The heater plate, could be rendered in operable/by operable any of the methods described, but with the water chamber in place in both configuration.

7. Cold passover

Whereas the system in Figure 3 includes at least the water chamber this could operate in both humidified and non humidified modes. For example the heater plate need not be initially supplied. The heater plate may be supplied but not activated.

Activating the heater plate could occur for example:

1. Heater plate control is by a rotary potentiometer 108. This can be incapacitated by a lock to physically prevent the potentiometer from turning. Upgrade to active humidification requires a second key to remove the potentiometer lock and activate the heater.

2. Heater control is by a setting in a menu accessed by buttons. Upgrade to active humidification requires a PIN number to activate the heater plate.

Referring to Figure 5 the key pad 500 is shown.

8. Heated Tube

The system could include a heated tube to deliver the gas to avoid condensation. Again this might be incapacitated initially.

Activating the heated tube control could occur by example:

1. Heater tube control by a rotary potentiometer, which is locked to physically prevent the potentiometer from turning. Upgrade requires a third key to remove the heated tube potentiometer lock and activate the heated tube.

2. Heated tube control by a setting in a menu accessed by buttons. Upgrade requires a PIN number to activate the heated tube.

Example upgrade kits could be:

Cold passover kit: Contains a chamber, key #1 to remove cover.

Heated humidification kit: Contains chamber, key #1 to remove cover and key #2 to remove the potentiometer lock OR a PIN number to activate the heater.

Heated tube kit: Contains chamber, key #1 to remove cover, key #2 to remove the potentiometer lock OR a PIN number to activate the heater. Key #3 to remove the heated tube potentiometer lock OR a second PIN number.

9. Other Functionality Upgrade

The electronic or mechanical key could also be used to upgrade other functionality. For example the applicant has identified it might be desirable to store and/or display data in relation to patient compliance, or use of the treatment.

Referring to Figure 5 we see a screen 502 for display of such compliance data. Depending on the key used example levels of functionality are given below:

Option 1: Machine displays no information.

Option 2: Machine displays machine run time only.

Option 3: Machine displays summary data on the display. For example, average hours complied per night used.

Option 4: Full compliance data download. All the day to data stored in the machine can be downloaded to a PC for analysis. Summary data would also be displayed.

It would be possible to activate any of these options by entering a suitable PIN number, or any other method, previously described or not.

This method could also apply to upgrading any function of the machine such as different levels of delivered pressure for inhalation versus exhalation and autosetting the pressure level.

DATED THIS 26TH DAY OF SEPTEMBER 03
AJ PARK
PER
AGENTS FOR THE APPLICANT

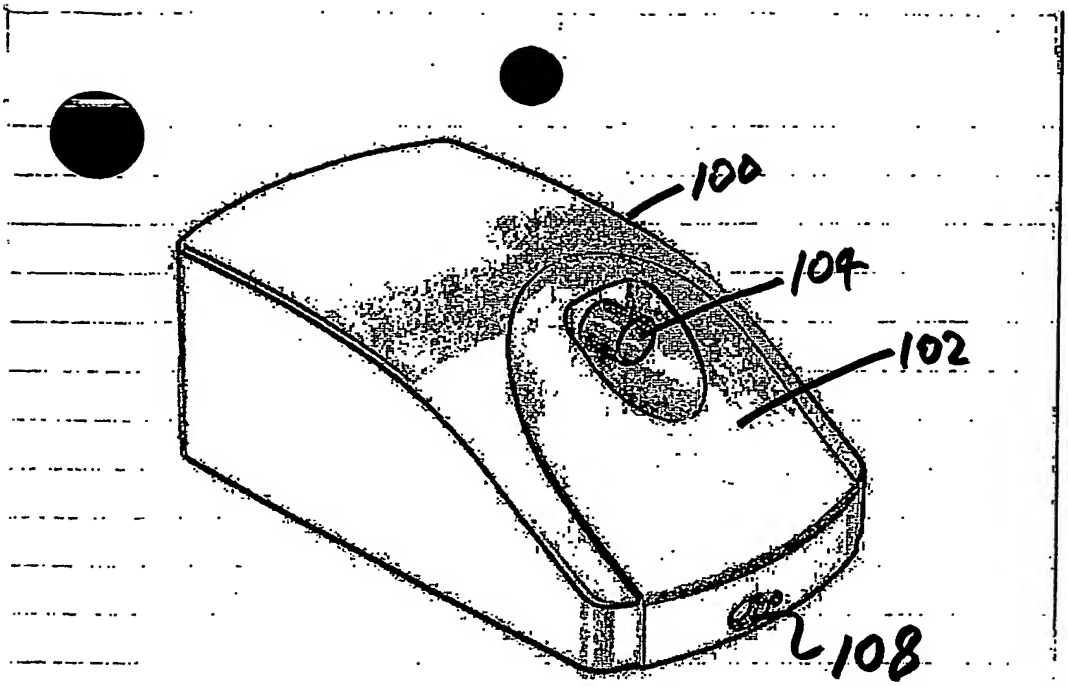

FIG 1

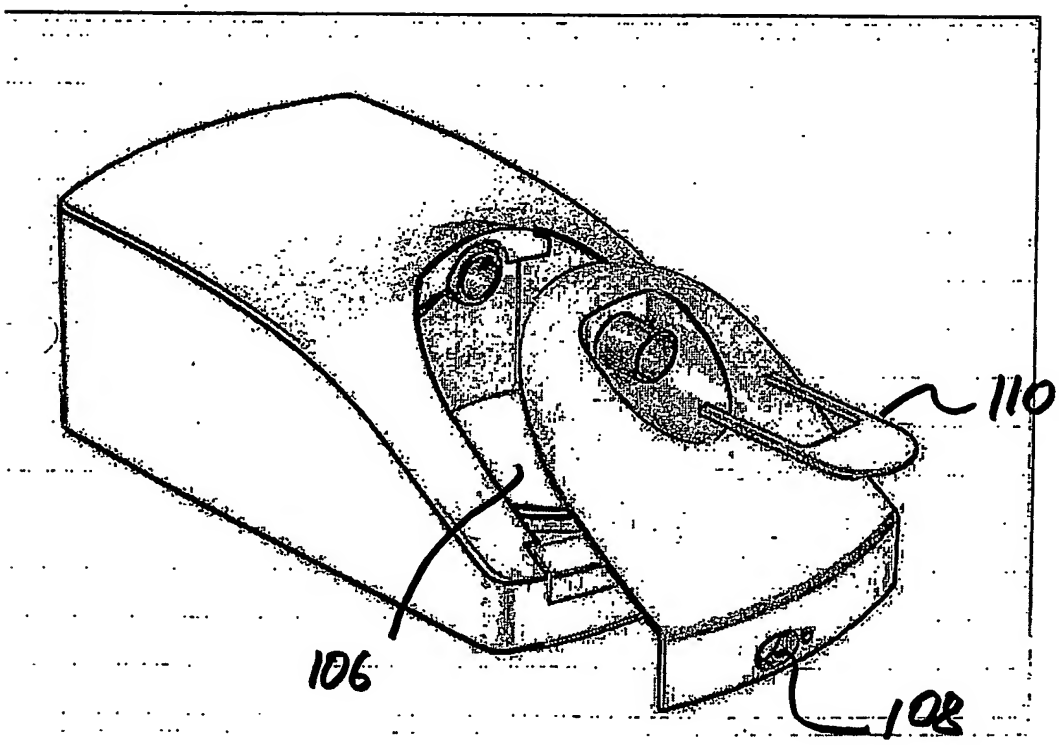

FIG 2A

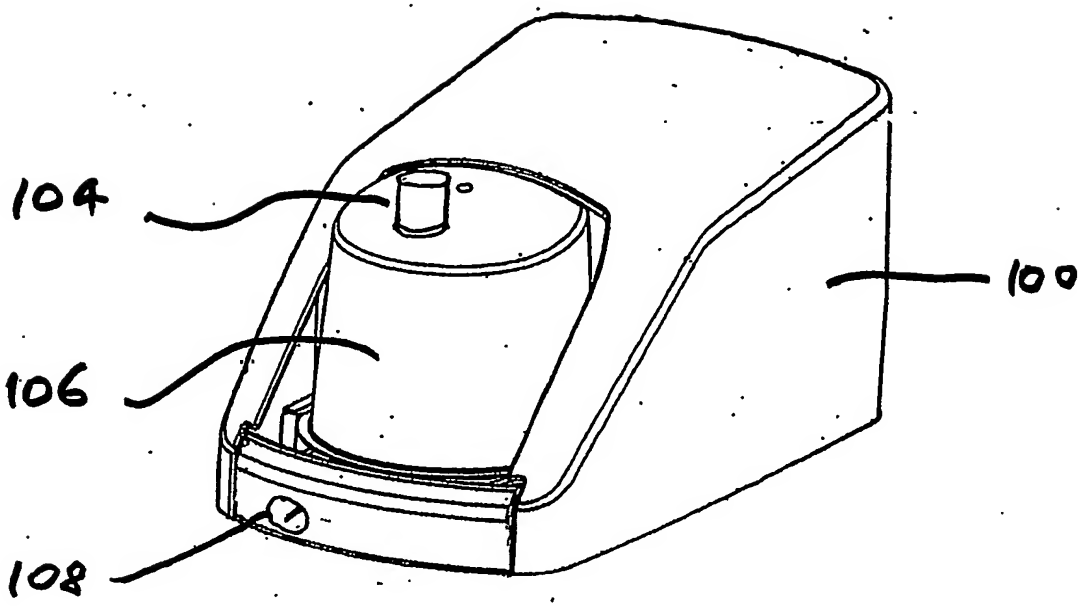

Figure 3

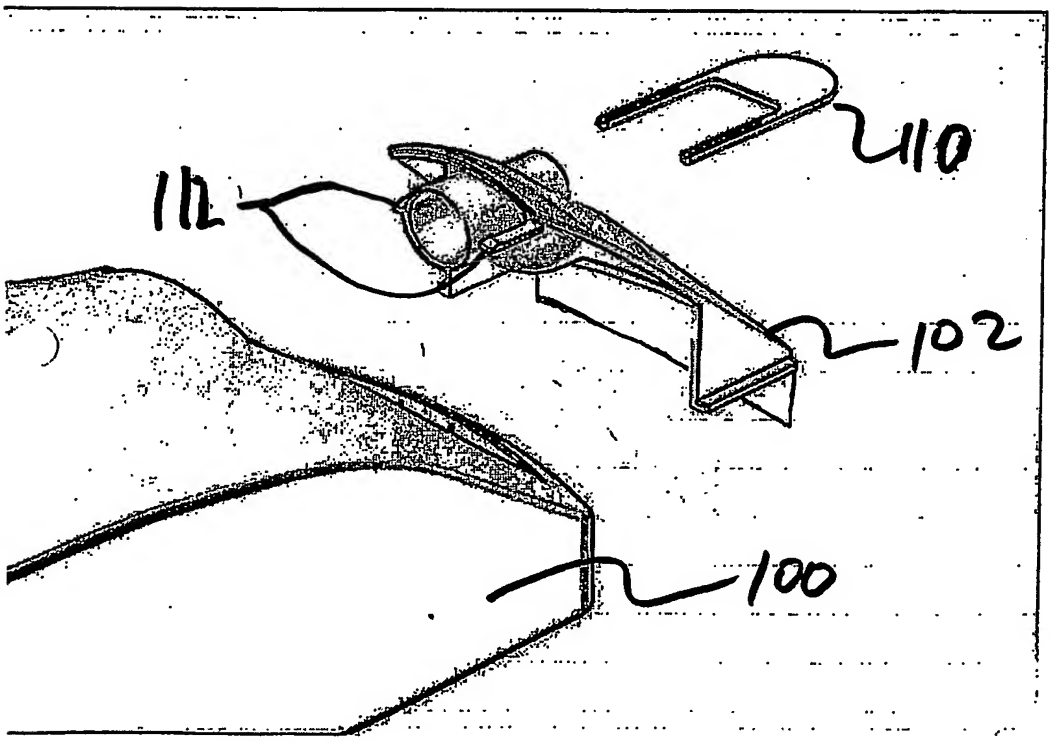

FIG 2B

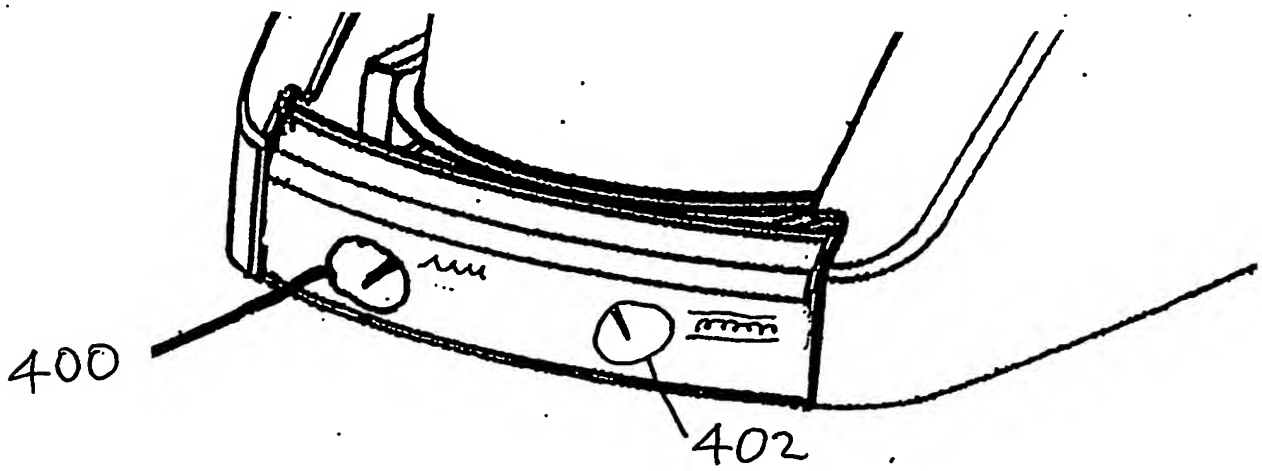

FIG. 4

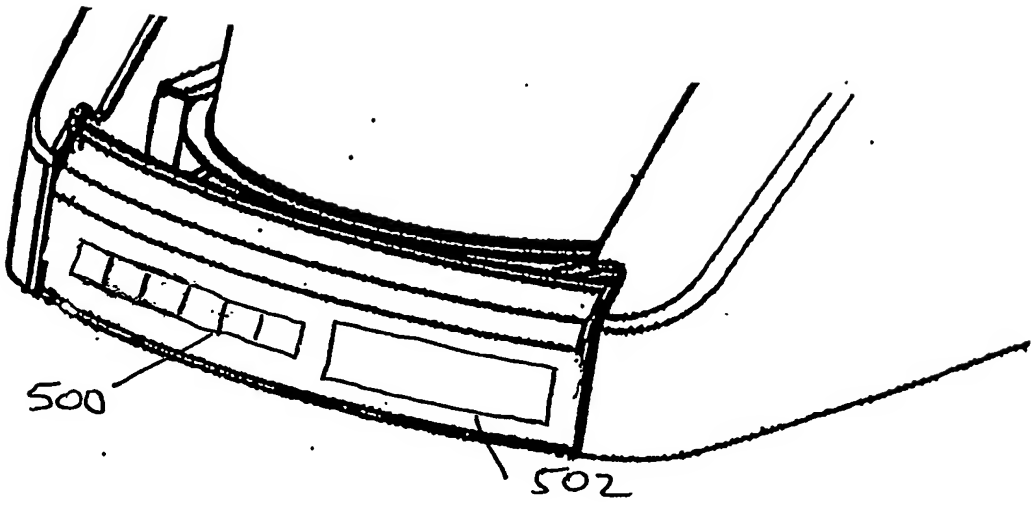

FIG. 5